

WHAT IS CLAIMED IS:

- 1 1. A method for manufacture of autograft, allograft and xenograft implants which
2 comprises assembling such implants from smaller pieces of graft materials to
3 form a larger graft implant product.

- 1 2. A kit comprising assemblable parts of autograft, allograft and xenograft implants
2 for assembling such implants from smaller pieces of graft materials to form a
3 larger graft implant product which may be formed in the course of a surgical
4 procedure to precisely meet the needs of a given patient or procedure.

- 1 3. A method of strengthening or reinforcing autograft, allograft and xenograft
2 implants which comprises assembling such implants from smaller pieces of graft
3 materials to form a larger graft implant product.

- 1 4. The method of claim 3 wherein the reinforced product is cancellous bone into
2 which is inserted reinforcing material.

- 1 5. The method according to claim 4 wherein said reinforcing material comprises
2 cortical bone.

- 1 6. A graft implant comprising any one or combinations of allograft materials,
2 autograft materials, xenograft materials, synthetic materials, metallic materials
3 assembled into a an assembled implant which is assembled into a single graft by
4 use of reinforcing material to hold the constituent pieces of graft materials
5 together.

- 1 7. The graft implant according to claim 6 wherein said reinforcing material
2 comprises cortical bone.

1 8. The graft implant according to claim 6 wherein said any one or combinations of
2 allograft materials, autograft materials, xenograft materials, synthetic materials,
3 metallic materials are pretreated by a process comprising removing associated
4 non-bone adventitious materials from a bone graft to provide a cleaned bone graft,
5 contacting the cleaned bone graft with defatting solutions to provide a cleaned
6 defatted bone graft, and contacting said cleaned defatted bone graft with a
7 chaotropic agent to remove non-collagenous or non-structural collagen proteins.

1 9. The graft implant according to claim 8 wherein said chaotropic agent is selected
2 from urea, guanidinium hydrochloride, Tween, TritonX-100, TNBP, SDS, and
3 mixtures of these agents.

1 10. The graft implant according to claim 6 wherein said any one or combinations of
2 allograft materials, autograft materials, xenograft materials, synthetic materials,
3 metallic materials are pretreated by a process comprising cleaning, perfusion and
4 passivation process which comprises cyclic exposure of said implant to increased
5 and decreased positive or negative pressures, or both.

1 11. The graft implant according to claim 10 wherein a cleaning solution used during
2 the cleaning step is selected from the group consisting of: sterile water, Triton X-
3 100, TNBP, 3% hydrogen peroxide, a water-miscible alcohol, saline solution
4 povidone iodine, ascorbic acid solution, aromatic or aliphatic hydrocarbons,
5 ethers, ketones, amines, urea, guanidine hydrochloride, esters, glycoproteins,
6 proteins, saccharides, enzymes, gaseous acids or peroxides, and mixtures thereof.

1 12. The graft implant according to claim 6 wherein the assembled implant is pre-
2 treated or treated after assembly to incorporate biologically active or inert
3 materials.

1 13. An implant comprising segments of cortical bone, cancellous bone, cortical-
2 cancellous bone, or combinations thereof pinned to each other by means of

3 cortical bone pins, wherein, prior to assembly or after assembly, the graft
4 materials are soaked, infused, impregnated, coated or otherwise treated with bone
5 morphogenetic proteins (BMP's), antibiotics, growth factors, nucleic acids,
6 peptides, or combinations thereof.

1 14. The implant according to claim 6 comprising an assembled cancellous block, or
2 dowel, harvested from the iliac crest or another suitable site to form a Cloward
3 Dowel, iliac crest wedge, or cancellous bone block, dowel, reinforced by insertion
4 therein of cortical bone pins.

1 15. The implant according to claim 6 comprising a cortical bone implant reinforced
2 by insertion therein of at least one cortical bone pin.

1 16. The implant according to claim 6 comprising an assembled implant comprising
2 different segments of cortical bone, cancellous bone or both.

1 17. The implant according to claim 6 comprising an assembled implant comprising
2 different segments of cortical bone, cancellous bone, demineralized cortical or
3 cancellous bone, synthetic material, and combinations thereof.

1 18. The implant according to claim 17 wherein insertion of reinforcing pins provides
2 an implant with multiple load-bearing pillars.

1 19. The implant according to claim 18 wherein said pins protrude from the surface of
2 the implant to engage with inferior, superior or both surfaces of bone between
3 which the implant is inserted.

1 20. The implant according to claim 19 which is a spinal implant.

1 21. The implant according to claim 19 comprising a cancellous portion of bone
2 implant that has been compression molded, and then affixed to other portions of
3 cortical or cancellous bone machined according to different or similar principles.

1 22. The implant according to claim 6 in the form of a tapered dowel.

1 23. A method of repairing a bone implant which comprises insertion therein of at
2 least one cortical bone pin.

1 24. The method according to claim 23 which further comprises affixing a piece of
2 bone to an existing bone implant by affixing said piece of bone to said cortical
3 bone pin.

1 25. The method according to claim 1 for making an instrument for insertion of other
2 implants.

1 26. The method according to claim 24 which is an implant driver.

1 27. A method for salvaging an implant that does not meet manufacturing
2 specifications which comprises insertion of at least one cortical bone pin at a site
3 to reinforce said site such that in combination with said at least one cortical bone
4 pin, said implant meets manufacturing specifications.

1 28. An assembled implant comprising a first bone segment pinned to a second bone
2 segment with a flexible tissue affixed between said first bone segment and said
3 second bone segment

5 29. The assembled implant according to claim 28 wherein said first and second bone
6 segments are affixed to each other by means of at least one cortical bone pin.

1 30. An assembled graft implant comprising two or more individual segments fastened
2 together, said implant comprising at least one demineralized bone segment and at
3 least one mineralized bone segment.

1 31. The assembled graft implant of claim 30, wherein said at least one demineralized
2 bone segment comprises a region of mineralized bone.

1 32. The assembled graft implant of claim 30, wherein said demineralized or
2 mineralized segments are made from cortical bone, cancellous bone or both.

1 33. An assembled graft implant comprising two or more individual segments fastened
2 together, said implant comprising at least one synthetic segment and at least one
3 demineralized bone segment.

1 34. The assembled graft implant of claim 33, wherein said demineralized bone
2 segment comprises a region of mineralized bone.

1 35. The assembled graft implant of claim 33, wherein said synthetic segment is
2 comprised of stainless steel, titanium, cobalt chromium-molybdenum alloy, nylon,
3 polycarbonate, polypropylene, polyacetal, polyethylene oxide and its copolymers,
4 polyvinylpyrrolidone, polyacrylates, polyesters, polysulfone, polylactide, poly(L-
5 lactide) (PLLA), poly(D,L-lactide) (PLA), poly(glycolide) (PGA), poly(L-lactide-
6 co-D,L-Lactide) (PLLA/PLA), poly(L-lactide-co-glycolide) (PLA/PGA),
7 poly(glycolide-co-trimethylene carbonate) (PGA/PTMC), polydioxanone (PDS),
8 polycaprolactone (PCL), polyhydroxybutyrate (PHBT), poly(phosphazenes),
9 poly(D,L-lactide-co-caprolactone) (PLA/PCL), poly(glycolide-co-caprolactone)
10 (PGA/PCL), poly(phosphazene ester), polyanhydrides, polyvinyl alcohol,
11 hydrophilic polyurethanes, and a combination of one or more bioabsorbable
12 polymers.

1 36. The assembled graft implant of claim 33, wherein said at least one synthetic
2 segment comprises a first end and a second end, and wherein a demineralized
3 bone segment or a mineralized bone segment is attached to said first end or said
4 second end.

1 37. An assembled graft implant comprising two or more individual segments
2 fastened together, said implant comprising at least one synthetic segment and at
3 least one mineralized bone segment.

1 38. The assembled graft implant of claim 37, wherein said synthetic segment is
2 comprised of stainless steel, titanium, cobalt chromium-molybdenum alloy, and a
3 plastic of one or more members selected from the group consisting of nylon,
4 polycarbonate, polypropylene, polyacetal, polyethylene oxide and its copolymers,
5 polyvinylpyrrolidone, polyacrylates, polyesters, polysulfone, polylactide, poly(L-
6 lactide) (PLLA), poly(D,L-lactide) (PLA), poly(glycolide) (PGA), poly(L-lactide-
7 co-D,L-Lactide) (PLLA/PLA), poly(L-lactide-co-glycolide) (PLA/PGA),
8 poly(glycolide-co-trimethylene carbonate) (PGA/PTMC), polydioxanone (PDS),
9 polycaprolactone (PCL), polyhydroxybutyrate (PHBT), poly(phosphazenes),
10 poly(D,L-lactide-co-caprolactone) (PLA/PCL), poly(glycolide-co-caprolactone)
11 (PGA/PCL), poly(phosphazene ester), polyanhydrides, polyvinyl alcohol,
12 hydrophilic polyurethanes, and a combination of one or more bioabsorbable
13 polymers.

1 39. An assembled graft implant comprising two or more individual segments fastened
2 together, wherein said assembled graft comprises at least one segment comprised
3 of demineralized bone, mineralized bone, demineralized bone having a
4 mineralized region, or a synthetic material, and at least one other segment
5 fastened thereto that is comprised of demineralized bone, mineralized bone,
6 demineralized bone having a mineralized region, or a synthetic material.

1 40. A graft segment configured for assembly with at least one other segment, wherein
2 said graft segment comprises at least one mineralized bone region and at least one
3 demineralized bone region.

1 41. The graft segment of claim 40, wherein said mineralized bone region is attached
2 to or integrated with said demineralized bone region.

1 42. A graft segment according to claim 40, wherein said graft segment comprises a
2 central mineralized bone region and at least one demineralized bone region
3 integrated with said central mineralized bone region and positioned on one or
4 more sides of or surrounding said mineralized bone region.

1 43. A mixed composition segment configured for assembly with at least one other
2 segment, said mixed composition segment comprising a region comprised of
3 mineralized bone, demineralized bone or a synthetic material that is attached to or
4 integrated with another region comprised of mineralized bone, demineralized
5 bone or a synthetic material.

1 44. The mixed composition segment of claim 43, additionally assembled with at least
2 one other graft segment.

1 45. A method for manufacture of a mixed-composition segment for autograft,
2 allograft and xenograft graft implants comprising contacting a region of a
3 mineralized bone segment with a demineralizing solution for a period of time
4 sufficient to achieve a desired level of demineralization to said region.

1 46. The method of claim 45 further comprising removing a sufficient quantity of said
2 demineralizing solution from said first region to prevent a toxic or an
3 inflammatory response to said segment upon implantation into a patient in need
4 thereof.

1 47. The method of claim 46, wherein said contacting is repeated for at least one
2 additional region, and said removing step is done to said at least one additional
3 region at the same time or at a different time as for said first region.

1 48. A mixed-composition segment produced by the method of claim 45.

1 49. A mixed-composition segment produced by the method of claim 45, wherein at
2 least one region of said mixed-composition segment is mineralized bone, and at
3 least one region of said mixed-composition segment is demineralized bone.

1 50. A mixed-composition segment produced by the method of claim 45, wherein one
2 region of said mixed-composition segment is mineralized, and one or more
3 regions of said mixed-composition segment are demineralized, wherein said one
4 or more regions surround or sandwich said region of mineralized bone.

1 51. A method for manufacture of a mixed-composition segment for autograft,
2 allograft and xenograft graft implants comprising
3 a. contacting a first piece of graft material comprising bone with a
4 demineralizing solution for a period of time sufficient to achieve a desired
5 level of demineralization to said first piece; and
6 b. bonding or otherwise intimately attaching a portion (region) of said first
7 piece of demineralized graft material with a second piece of graft material,
8 said second piece of graft material being mineralized, demineralized, or
9 synthetic, such that said bonding or intimately attaching results in a single
10 integral mixed-composition segment; and
11 c. optionally, removing a sufficient quantity of said demineralizing solution
12 from said first region to prevent a toxic or an inflammatory response to
13 said segment upon implantation into a patient in need thereof.

1 52. The method of claim 51, wherein step (a) is repeated for at least one additional
2 piece, and step (b) is repeated to attach each at least one additional piece to form a
3 multi-piece (multi-region) mixed-composition segment.

1 53. A mixed-composition segment produced by the method of claim 51.

1 54. A mixed-composition segment produced by the method of claim 51, wherein at
2 least one region of said mixed-composition segment is mineralized bone, and at
3 least one region of said mixed-composition segment is demineralized bone.

1 55. A mixed-composition segment produced by the method of claim 51, wherein one
2 region of said mixed-composition segment is mineralized bone, and one or more
3 regions of said mixed-composition segment are demineralized bone, wherein said
4 demineralized bone regions surround or sandwich said region of mineralized
5 bone.

1 56. A kit comprising assemblable parts of autograft, allograft, xenograft and synthetic
2 segments for assembling mixed-composition implants from smaller pieces of graft
3 materials to form a larger graft implant product which may be formed in the
4 course of a surgical procedure to precisely meet the needs of a given patient or
5 procedure, and comprising at least one mixed-composition segment among said
6 assemblable parts.

1 57. A method of strengthening or reinforcing a mixed-composition segment for
2 autograft, allograft and xenograft graft implants which comprises assembling said
3 mixed-composition segment from smaller pieces of graft materials to form a
4 larger mixed-composition segment.

1 58. The method of claim 57 wherein said mixed-composition segment comprises
2 cancellous bone in combination with demineralized bone.

1 59. The method of claim 57 wherein the mixed-composition segment comprises
2 cortical bone in combination with demineralized bone.

1 60. An implant comprising segments of cortical bone, cancellous bone, cortical-
2 cancellous bone, or combinations thereof pinned to each other by means of
3 cortical bone pins, wherein, prior to assembly or after assembly, the graft
4 materials are soaked, infused, impregnated, coated or otherwise treated with bone
5 morphogenetic proteins (BMP's), antibiotics, growth factors, nucleic acids,
6 peptides, sodium hyaluronate, hyaluronic acid, polysulfated glycosaminoglycans,
7 or combinations thereof, and wherein, at least one of said segments is a mixed-
8 composition segment or demineralized bone.

1 61. An assembled implant comprising a first bone segment pinned to a second bone
2 segment, and comprising a flexible tissue affixed between said first bone segment
3 and said second bone segment, wherein said first bone segment is a mixed-
4 composition segment.

1 62. An assembled implant bone graft comprising at least two individual segments
2 joined together, and synthetic scaffolding material, wherein said synthetic
3 scaffolding material passes through and/or surrounds said segments, thereby
4 providing structural support to at least one of said at least two individual
5 segments.

1 63. An assembled bone graft comprising:
2 a. a first graft segment comprising at least one mineralized bone region, and
3 at least one demineralized bone region; and comprising at least one hole;
4 b. at least one other graft segment comprising at least one hole; and
5 c. at least one connector;
6 d. whereby the first graft segment and the at least one other graft segment are
7 joined physically by said at least one connector.

1 64. The bone graft of claim 63, wherein said first graft segment and said at least one
2 other graft segment are joined physically by means of at least one pin, rod, bar,
3 post or other linear connector passing through said at least one hole in said first
4 graft segment which is arranged to align with said at least one hole of said other
5 graft segment.

1 65. The bone graft of claim 63, additionally comprising a synthetic support structure
2 that encompasses all or a part of said composite bone graft whereby the synthetic
3 support structure bears load that would otherwise bear on at least one of said graft
4 segments.

1 66. The bone graft of claim 65, wherein said synthetic support structure is comprised
2 of a biocompatible material selected from the group consisting of stainless steel,
3 titanium, cobalt chromium-molybdenum alloy, and a plastic of one or more
4 members selected from the group consisting of nylon, polycarbonate,
5 polypropylene, polyacetal, polyethylene oxide and its copolymers,
6 polyvinylpyrrolidone, polyacrylates, polyesters, polysulfone, polylactide, poly(L-
7 lactide) (PLLA), poly(D,L-lactide) (PLA), poly(glycolide) (PGA), poly(L-lactide-
8 co-D,L-Lactide) (PLLA/PLA), poly(L-lactide-co-glycolide) (PLA/PGA),
9 poly(glycolide-co-trimethylene carbonate) (PGA/PTMC), polydioxanone (PDS),
10 polycaprolactone (PCL), polyhydroxybutyrate (PHBT), poly(phosphazenes),
11 poly(D,L-lactide-co-caprolactone) (PLA/PCL), poly(glycolide-co-caprolactone)
12 (PGA/PCL), poly(phosphazene ester), polyanhydrides, polyvinyl alcohol,
13 hydrophilic polyurethanes, and a combination of one or more bioabsorbable
14 polymers.

1 67. A graft implant comprising any one or combinations of allograft materials,
2 autograft materials, xenograft materials, synthetic materials, and metallic
3 materials assembled into an assembled implant which is assembled into a single
4 graft by use of reinforcing material to hold the constituent pieces of graft
5 materials together, and comprising at least one mixed-composition segment.

1 68. The graft implant of claim 67 wherein said reinforcing material comprises cortical
2 bone.

1 69. The graft implant of claim 67 wherein the assembled implant is pre-treated or
2 treated after assembly to incorporate biologically active or inert materials.

1 70. The implant of claim 67 comprising an assembled cancellous block, or dowel,
2 harvested from the iliac crest or another suitable site to form a Cloward Dowel,
3 iliac crest wedge, or cancellous bone block, dowel, reinforced by insertion therein
4 of cortical bone pins.

1 71. The implant of claim 67 comprising a cortical bone implant reinforced by
2 insertion therein of at least one cortical bone pin.

1 72. The implant of claim 67 comprising an assembled implant comprising different
2 segments of cortical bone, cancellous bone or both.

1 73. The implant of claim 67 in the form of a tapered dowel.

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3 74. The implant of claim 67 comprising an assembled implant comprising different
4 segments of cortical bone, cancellous bone, demineralized cortical or cancellous
5 bone, or synthetic material, or combinations thereof.

1 75. The implant of claim 71 wherein insertion of reinforcing pins provides an implant
2 with multiple load-bearing pillars.

1 76. The implant of claim 75 wherein said pins protrude from the surface of the
2 implant to engage with inferior, superior or both surfaces of bone between which
3 the implant is inserted.

1 77. The implant of claim 67 which is a spinal implant.

1 78. The implant according to claim 67 comprising a cancellous portion of bone
2 implant that has been compression molded, and then affixed to other portions of
3 cortical or cancellous bone machined according to different or similar principles.

1 79. A bone implant comprising:
2 a. two or more bone segments,
3 b. at least one biocompatible connector,
4 c. wherein said at least one biocompatible connector fastens together said
5 two or more bone segments to form an assembled bone implant, said at
6 least one biocompatible connector does not comprise an adhesive.

1 80. The bone implant of claim 79, wherein at least one of said two or more bone
2 segments is a mixed composition segment.

1 81. An assembled bone graft comprising at least three segments, each said segment
2 comprising a first edge and a second edge at a side opposite from the first edge,
3 the first and second edges having interlocking structures mateable with an
4 adjacent edge of an adjacent segment, whereby each said segment's first and
5 second edges interlock with the edges of adjacent segments.

1 82. An assembled bone graft comprising at least three non-coplanar segments, each
2 said segment comprising a first mateable edge and a second mateable edge, each
3 of said mateable edges being mateable with an adjacent mateable edge of an
4 adjacent segment, whereby said assembled bone graft is assembled by mating said
5 first edges and said second edges of said segments positioned adjacent to one
6 another.

1 83. The assembled bone graft of claim 82, wherein said mateable edges interlock, and
2 are selected from the group of joint types consisting of ball and socket, tongue
3 and groove, and mortise and tenon.

1 84. The assembled bone graft of claim 82, additionally comprising at least one band
2 of flexible, non-stretchable material wrapped around the circumference of said
3 assembled bone graft.

1 85. The assembled bone graft of claim 82, wherein at least one of said segments is
2 comprised of a material selected from the group consisting of demineralized bone,
3 mineralized bone, a combination of demineralized and mineralized bone.

1 86. The assembled bone graft of claim 82, wherein at least one of said segments is
2 comprised of a material selected from the group consisting of cortical bone,
3 cancellous bone, and a combination of cortical and cancellous bone.

1 87. The assembled bone graft of claim 82, wherein at least one of said segments is
2 comprised of any one or combinations of allograft materials, autograft materials,
3 xenograft materials, synthetic materials, and metallic materials assembled into a
4 segment.

1 88. An assembled bone graft comprising a first and a second arcuate-shaped segment,
2 each segment comprising two interlocking edges, whereby each said edge of said
3 first segment interlocks with an edge of said second segment, forming an
4 assembled bone graft with an open channel between said first and second
5 segments.

1 89. A bone tendon bone-type graft useful in orthopedic surgery comprising at least
2 one block and a flexible band attached to said at least one block.

1 90. The bone tendon bone-type graft of claim 89, wherein at least one block of the at
2 least one block is comprised of a synthetic material, and the flexible band is
3 comprised of allograft or xenograft tendon, ligament, or processed dermis.

1 91. The bone tendon bone-type graft of claim 89, wherein at least one of the at least
2 one block is comprised of cortical bone, cancellous bone, cortico-cancellous bone,
3 or a combination of these, and the flexible band is comprised of a synthetic
4 material.

1 92. The bone tendon bone-type graft of claim 91, wherein said synthetic material is
2 comprised of a biocompatible material selected from the group consisting of
3 nylon, polycarbonate, polypropylene, polyacetal, polyethylene oxide and its
4 copolymers, polyvinylpyrrolidone, polyacrylates, polyesters, polysulfone,
5 polylactide, poly(L-lactide) (PLLA), poly(D,L-lactide) (PLA), poly(glycolide)
6 (PGA), poly(L-lactide-co-D,L-Lactide) (PLLA/PLA), poly(L-lactide-co-
7 glycolide) (PLA/PGA), poly(glycolide-co-trimethylene carbonate) (PGA/PTMC),
8 polydioxanone (PDS), polycaprolactone (PCL), polyhydroxybutyrate (PHBT),
9 poly(phosphazenes), poly(D,L-lactide-co-caprolactone) (PLA/PCL),
10 poly(glycolide-co-caprolactone) (PGA/PCL), poly(phosphazene ester),
11 polyanhydrides, polyvinyl alcohol, and hydrophilic polyurethanes.

1 93. The bone tendon bone-type graft of claim 91, wherein at least one of the at least
2 one block is comprised of an assembled bone graft.

1 94. The bone tendon bone-type graft of claim 92, wherein the assembled bone graft is
2 comprised of at least one mixed-composition segment.

1 95. A method of assembling an assembled implant to obtain a desired interference fit,
2 comprising:
3 a. vacuum drying at least one bone pin to obtain a desired size reduction;
4 b. measuring the diameter of the at least one bone pin after vacuum drying;
5 c. making at least one hole in at least one bone piece to be assembled with
6 the at least one bone pin, wherein the hole is smaller than the diameter of
7 the at least one bone pin to obtain an interference fit;

8 d. assembling the at least one bone pin with the at least one bone piece by
9 inserting each of the at least one pin(s) through the at least one hole(s) to
10 form the assembled implant; and
11 e. freeze drying the assembled implant;
12 whereby the interference fit(s) between the at least one bone pin and the at
13 least one hole in the at least one bone piece fall within a desired range.

1 96. The method of claim 95 wherein the at least one bone pin is comprised of cortical
2 bone, and optionally at least one of the at least one bone piece is comprised of
3 cortical bone.

1 97. The method of claim 96 wherein the desired range for the interference fit is 0.001
2 to 0.003 inches.

1 98. The method of claim 96 wherein the vacuum drying is at room temperature, is
2 conducted at a negative pressure of approximately 100 milliTorr, and lasts at
3 least five hours.

1 99. An assembled implant comprising at least two substantially planar segments,
2 wherein at least one of said at least two substantially planar segments comprise at
3 least one slot defined thereon, and wherein said at least two substantially planar
4 segments are fastened together by sliding said at least one slot of at least one
5 planar segment over another substantially planar segment.

1 100. The assembled implant of claim 99, said implant comprising a first substantially
2 planar segment and a second substantially planar segment, wherein said first and
3 second substantially planar segments comprise a slot longitudinally defined
4 thereon such that said first and second substantially planar segments comprise a slotted section and a body section, and wherein said first and second substantially
5 planar segments are fastened together by sliding the slotted section of each over
6 the body portion of the other.
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1 101. A bone-tendon graft comprising at least one assembled bone block, wherein said
2 bone block is comprised of mineralized bone, demineralized bone or a synthetic
3 material, or a mixed composition; and at least one flexible band attached to said at
4 least one bone block, wherein said band is comprised of demineralized bone or of
5 a synthetic material.